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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,698	06/01/2001	Dennis D. Elsberry	P-3226.04	3939

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EXAMINER	
THISSELL, JEREMY	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 07/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/872,698	Applicant(s) ELSBERRY, DENNIS D.	
	Examiner Jeremy T. Thissell	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44,45,47-57 and 65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *44 and 45* is/are allowed.

6)☒ Claim(s) *47-57 and 65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Frisch (US 4,100,246).

Frisch teaches all the claimed subject matter including the method of adjusting outer and inner tubes of a tubular medical device by either heating or exposing the outer tube to a solvent so as to expand it and allow the inner tube to be selectively adjusted for length (see col. 5, lines 3-45), and further teaches implantation of the device in a patient (col. 1, lines 53+).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al (US 5,462,523) in view of Miller (US 4,767,400) and Frisch.

Samson teaches a drug delivery catheter having a non-porous outer sleeve, and a porous inner sleeve that protrudes beyond the distal end of the outer sleeve so as to allow for perfusion of drugs through the pores. However, Samson does not teach that the outer and inner sleeve are adjustable relative to one another and that the device is implanted in the hippocampus or lateral ventricle.

Miller teaches a similar device to Samson (i.e. a catheter with porous and non-porous segments). It would have been obvious to introduce the device of Samson into any part of the body where it is deemed to be useful by one of ordinary skill in the art. Miller demonstrates one such location.

Frisch teaches the method of adjusting outer and inner tubes of a tubular medical device by either heating or exposing the outer tube to a solvent so as to expand it and allow the inner tube to be selectively adjusted for length. It would have been obvious to make the device of Samson adjustable to provide a variable surface area of porous tube for drugs to be introduced through, since it is well within the level of ordinary skill in the art to make a device adjustable.

Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al (US 5,462,523) in view of Miller (US 4,767,400) and Frisch as applied to claim 55 above, and further in view of Olney (US 5,767,130).

Samson, Miller, and Frisch teach all the claimed subject matter except for injecting drugs into the hippocampus or lateral ventricle as a method of treating Alzheimer's Disease. Olney teaches this well-known method (col. 10, lines 11-19; col.

18, lines 32-50). It would have been obvious to one of ordinary skill in the art to use a device such as Miller to inject fluids rather than withdraw fluids, since Olney teaches that it is well-known to inject drugs into the same area of the brain.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 47-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,093,180. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim the same core subject matter, that is the method of adjusting outer and inner tubes of a tubular medical device by either heating or exposing the outer tube to a solvent so as to expand it and allow the inner tube to be selectively adjusted for length. US 6,093,180 also teaches inserting the device into a patient (col. 6, line 12).

Allowable Subject Matter

Claims 44 and 45 are allowable over the prior art of record.

The prior art does not teach or fairly suggest the combination of the claimed catheter assembly/adjustment and the use in the hippocampus or lateral ventrical to administer doses of indomethacin. As discussed in the parent case, the introduction of indomethacin to the ventrical is known [see rejections using Corrales (US Pat No 3,941,119) in view of Rogers et al ("Clinical Trial of Indomethacin in Alzheimer's Disease")]. However, there is no motivation to assemble the device used by Corrales in the manner claimed in claims 44/45, i.e. coaxial tubes wherein the outer tube is expanded when exposed to a factor (e.g. heat or solvent) so that the inner tube can be adjusted telescopically with respect to the outer tube so as to provide a desired length.

Response to Arguments

Applicant's arguments filed 19 March 2002 have been fully considered but they are not persuasive.

Applicant's arguments are in large part moot due to new grounds of rejection. The examiner hereby addresses remaining pertinent arguments.

With regard to Frisch, the examiner points out that the lengths of the components are specific to particular parts of the patient's anatomy (col. 1, lines 54-63). Therefore the sizing will inherently be set appropriately for the patient (i.e. adult, child, male, female).

With regard to claims 55-57, Samson teaches that the device can be of various sizes depnding on the "service to which it is placed" (col. 4, lines 19-21), which in view of the teachings of Frisch immediately supra indicates the obviousness of the customization to an individual patient.

With regard to the double patenting rejection of claims 47-58, Applicant argued that the newly added limitations obviate this rejection. However, applicant merely added the customization to a patient, and the implantation of the catheter, both of which may be found in claim 1 of 6,093,180.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt
June 25, 2002

ANHTUAN T. NGUYEN
PRIMARY EXAMINER